IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 3:21-CV-634

NOTICE OF SUPPLEMENTAL AUTHORITY

Defendants respectfully write to provide this Court notice of a recently issued decision opining on the ultimate question before this Court: "whether HRSA correctly concluded that Lilly's" (and, by implication, Sanofi's) "contract pharmacy restrictions violate[] the statutory prohibition on overcharging covered entities." *See* ECF No. 144, Order on Mots. for Summ. J. at 39, *Eli Lilly v. Becerra* (*Lilly*), No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Oct. 29, 2021) (attached as Ex. A). Lilly's restrictions on covered entities' access to 340B-discounted drugs are similar to those adopted by Sanofi, in that both manufacturers impose unilateral, extra-statutory conditions on covered entities' access to 340B-priced drugs, and the Violation Letter issued to Lilly mirrors the letter issued to Sanofi and under review by this Court. In reviewing Lilly's policy, that court made plain that "[r]esolution of this issue turns on the interpretation of the 340B statute" and found that "[c]onstruing the 340B statute not to permit drug manufacturers to impose extra-statutory conditions on covered entities' access to discounted medications is not only a permissible construction," but "the construction that best aligns with congressional intent." *Id.* at 39, 49.

Specifically, the *Lilly* court held: "Plaintiffs' construction of the 'shall … offer' provision to authorize its refusal to honor the 340B price for covered entities' purchases based solely on delivery location or dispensing mechanism, thereby requiring covered entities to pay WAC prices for covered outpatient drugs if they do not operate an in-house pharmacy or fail to designate a single contract pharmacy Lilly approves for shipment, *directly conflicts with the statutory requirement* otherwise." Ex. A at 46 (emphasis added). Moreover:

> Congress's use of broad language in enacting this statute and specifically omitting any mention of where 340B drugs are to be delivered does not leave room for drug manufactures to unilaterally condition or control the availability of their 340B pricing to a particular delivery location of their choosing such that covered entities are prevented from accessing 340B pricing and required to purchase covered outpatient drugs at WAC prices. *The fairest and most reasonable interpretation* of the 340B statute would not authorize drug manufacturers to impose unilateral restrictions on the distribution of the drugs that 'would frustrate Congress' manifest purpose' in enacting the statute.

Id. at 46-47 (quoting *United States v. Hayes*, 555 U.S. 415, 426-27 (2009)) (emphasis added). The *Lilly* court also noted that it was "beyond [its] purview to determine whether purchases made using the replenishment model constitute diversion" because "there can be no dispute that Congress mandated that any concerns regarding diversion be addressed first through ADR procedures, not in federal litigation." *Id.* at 47 n.14 (citing 42 U.S.C. § 256b(d)(3)(B)(iv)). And although "Congress may at some point choose to amend the statute to directly address … issues" such as "the vast proliferation of contract pharmacy arrangements," "drug manufacturers may not usurp the role through unilateral extra-statutory restrictions." *Id.* at 49.

Notwithstanding its clear holding that HRSA's statutory interpretation is correct, the *Lilly* court set aside the letter as arbitrary and capricious, finding that the agency failed to explain its "change in position regarding its authority to enforce potential violations of the 340B statute connected to contract pharmacy arrangements." *Id.* at 52. In rendering that decision, the court agreed "that the agency has consistently espoused the view in non-binding guidance that drug

manufacturers must comply with their obligations under the 340B statute regardless of the manner in which the covered entity chooses to dispense the drugs and must accommodate all contract pharmacy arrangements that the government permits." *Id.* at 53. The court nonetheless found that the agency had been inconsistent in certain public statements about its enforcement abilities. Defendants respectfully note that one of the primary statements relied upon by the *Lilly* court, an unsourced email purportedly sent by an unnamed agency official to a trade-magazine reporter, is insufficient to credit as an official position of the agency and is not part of the administrative record on which review of the Violation Letter must be based. Even taken at face value, the unnamed official is quoted as stating that HRSA can enforce "a clear violation of the 340B statute."[1] More importantly, however, the statements cited by the *Lilly* court show that HRSA consistently has stated

[1] Nor do the other documents cited by the *Lilly* court evince any belief that the agency could not enforce 340B statutory requirements. The June 11, 2020 letter HRSA sent to Lilly said nothing whatsoever about enforcement of the statute, instead pointing out only that its contract-pharmacy guidance is not contained in binding regulations—a point not subject to dispute. VLTR_7590 (discussed Ex. A at 54). Elsewhere, as the *Lilly* court noted, HRSA acknowledged that it lacks an explicit grant of comprehensive rulemaking authority (Ex. A at 54, *citing*, *e.g.*, VLTR_3272), but that also is undisputed and has no bearing on the agency's ability to enforce the statute. Finally, the *Lilly* court pointed to a communication from a covered entity to HRSA, accurately explaining that the non-enforceability of guidance is immaterial because HRSA can enforce *the statute* against manufacturers. Ex. A at 54-55 (citing VLTR_3283). An email from a covered entity cannot be relied upon as evidence of HRSA's interpretation of its own authority—and even putting that aside, the cited communication is wholly consistent with HRSA's own view that it can enforce statutory requirements, not guidance. Taken together, HRSA's statements do not "espouse[] the view that it lacked enforcement authority regarding contract pharmacy use," *contra* Ex. A at 55, but merely that it lacked authority to enforce *guidance*—which by its nature is not binding.

This distinction explains HRSA's different approach where covered entities have been found during audits not to have adhered to various elements of HRSA's contract-pharmacy guidance. *See* Ex. A at 57 (discussing GAO Report findings on covered-entity compliance with guidance). As previously explained to this Court, HRSA's 1996 and 2010 guidances state that various provisions directed to covered entities' use of contract pharmacies are *suggested elements* to avoid duplicate-discounting and diversion violations, not requirements of the statute, so of course HRSA would not bring an enforcement action for failure to follow suggested provisions found in guidance. That is distinct from HRSA's interpretation that manufacturers not place conditions or restrictions on 340B-discount access, which derives from the statute itself. There is thus no conflict between HRSA declining to enforce guidance against covered entities and enforcing the statute against manufacturers, *contra id.*; at no time has HRSA disclaimed its ability to enforce the statute itself.

that its enforcement authority is limited *to violations of the statute itself*, not requirements found only in guidance, and there can be no dispute either that agency guidance is not legally enforceable or that Congress granted HHS authority to enforce *the statute* against manufacturers. *See Astra v. Santa Clara Cty.*, 563 U.S. 110, 117-21 (2011) (rejecting enforcement action by covered entities against drug maker and discussing extensively that Congress granted HRSA sole authority to enforce and oversee program compliance).

At bottom, however, vacatur of the May 17 letter issued to Lilly in no way undermines that court's plain holding that Lilly's policy (and, by implication, other manufacturers' policies imposing similar restrictions) violate the 340B statute itself. And because Lilly's policy has been deemed unlawful, continued imposition of those restrictions to overcharge covered entities and restrict their access to 340B drugs will continue to subject Lilly to liability under the statute, including the potential imposition of civil monetary penalties already being considered by the Office of the Inspector General and potential termination of its PPA (and a corresponding expulsion from Medicaid and Medicare Part B coverage) should Lilly persist in its unlawful behavior—even in the absence of the May 17 letter or a similar violation letter.[2]

Sanofi makes much of the nuances purportedly distinguishing its "integrity initiative" from other contract-pharmacy restrictions, such as Lilly's, but any such distinctions are without a difference because Sanofi's policy also "impose[s] extra-statutory conditions on covered entities' access to discounted medications," *see* Ex. A at 49. Defendants respectfully contend that the *Lilly* court correctly and persuasively found that HRSA's statutory interpretation is correct. This Court should similarly hold that Sanofi's extra-statutory restrictions are equally unlawful.

[2] Notably, Sanofi has not asked this Court to set aside the Violation Letter as arbitrary and capricious for failure to explain a purported change in position regarding the agency's authority to enforce the statute.

Respectfully submitted,

Dated: November 2, 2021

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